Letter to public sector clinicians re private sector patients transferring in on the FDC

Dear Colleague

As you are aware, in 2012, Dr Aaron Motsoaledi, South Africa's Minister of Health, announced the award of a new antiretroviral (ARV) tender, which, for the first time since the start of the ARV program, includes a triple fixed dose combination (FDC) tablet. This is a significant step forward for South Africa's national ARV program, enhancing cost effectiveness and simplifying the first-line regimen. However, initially, FDC supply will be insufficient to provide for all FDC-suited patients, as SA's FDC producers will need time to maximise production to provide sufficient FDC for all eligible patients.

As the initial FDC supply will be insufficient to provide all suitable patients, a gradual, phased approach to introducing the FDC treatment should help to ensure a smooth transition. The Department of Health (DoH) has recommended that the following patient groups be prioritised for FDC initiation/switch:

1. **Priority group 1**: All HIV-positive patients newly initiating ART - adults, adolescents and pregnant women (regardless of CD4 count) - and who do not have contra-indications to the FDC component drugs

2. **Priority group 2**: HIV-positive pregnant women and breastfeeding mothers currently stable on lamivudine (3TC), tenofovir (TDF) and efavirenz (EFV).

Of particular concern are patients who have been receiving, or been switched to, an FDC in the private healthcare sector. These patients may now opt to access public sector clinics for their ARVs. However, these patients are **not to be maintained** on their FDC, unless they fall into either priority group 1 (unlikely) or 2. They will need to be switched to the equivalent individual components of their treatment regimen. There should be no exceptions to this as retaining these patients on FDC may result in FDC stock outs. These patients will need to be counseled extensively, explaining why it is not possible to maintain them on the FDC, and to manage their expectations in this regard. Over time the availability of FDC stock will expand. Eventually these patients may be able to be switched back to the FDC but this should only happen once NDoH expands access beyond priority groups 1 and 2.

With the ongoing expansion of SA’s ARV programme, clinics are experiencing burgeoning populations of stable patients who are clinically well and virologically suppressed. Long-term retention in care of this group is proving problematic. However, the NDoH has decided that clinically stable patients receiving TDF, 3TC and EFV are initially to be prioritised below other groups during the period of this current tender. Furthermore, those patients who are
not included in the priority groups for the FDC, or are unable to take the FDC, will need to be counselled so that they understand why they are not being switched to an easier option.

The introduction of the FDC is a significant step forward for South Africa's national ARV program, and the Southern African HIV Clinicians’ Society fully supports the NDoH with the phasing in of the FDC. The Society urges all clinicians to adhere strictly to the NDoH priority groups in order to avoid FDC stock-outs and to help ensure a smooth transition to the FDC.

The Southern African HIV Clinicians Society